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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed motions to exclude the opinions of two regulatory experts, Drs. Suzanne Parisian and David Kessler. Docs. 7308, 7309. The motions are fully briefed, and the Court heard arguments on December 15, 2017. The Court will grant the motions in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves seven different versions of Bard IVC filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali. Each filter received premarket clearance from the Food and Drug Administration ("FDA").[1]

[1] For further discussion of IVC filters and the FDA regulatory process, see the Court's order addressing Defendants' summary judgment motion regarding preemption. Doc. 8872 at 2-5.

Each Plaintiff in this MDL received an implant of a Bard IVC filter and claims that the filter is defective and has caused serious injury or death. Plaintiffs allege that Bard filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1.

Bard disputes Plaintiffs' allegations, contending that complication rates for Bard filters are comparable to those of other IVC filters, and that the medical community is aware of the risks associated with IVC filters. Bard contends that the FDA's premarket clearance of its IVC filters and labels shows that the filters are safe and effective, and that Bard provided adequate warnings to implanting physicians.

The parties intend to use various expert witnesses at trial, including engineers, medical professionals, and regulatory experts. Plaintiffs have identified Drs. Parisian and Kessler as FDA regulatory experts. Dr. Parisian is a board-certified pathologist with a master's degree in biology. She served as an FDA medical officer in the early 1990s. Dr. Kessler is a former FDA Commissioner who holds a medical degree from Harvard Medical School and a law degree from the University of Chicago Law School. He is a professor of food and drug law, and serves as an advisor to pharmaceutical and biomedical companies.

Defendants agree that Drs. Parisian and Kessler are qualified, based on their knowledge, experience, and training, to serve as experts regarding the FDA regulatory process for medical devices. Defendants also agree that the FDA process is complex and beyond the experience of the average juror, and that opinions of regulatory experts therefore may prove helpful to the jury. Defendants argue, however, that the specific opinions and proposed testimony of Drs. Parisian and Kessler are inadmissible under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

II. Legal Standard.

Under Rule 702, an expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). The proponent of expert testimony has the ultimate burden of showing, by a preponderance of the evidence, that the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). But the trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. Rule 702's requirements, and the court's gatekeeping role, apply to all expert testimony, not solely to scientific testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

III. Dr. Parisian.

Dr. Parisian presents a difficult challenge. Her report is 257 pages long, unwieldy, often unfocused, and poorly organized. As another court aptly observed, "Dr. Parisian's report is a labyrinth that the Court cannot navigate." *Lopez v. I-Flow Inc.*, CV 08-1063-PHX-SRB, 2011 WL 1897548, at *10 (D. Ariz. Jan. 26, 2011). Numerous courts have excluded her FDA-related testimony because she fails to identify a clear methodology, engages in lengthy factual narratives, opines on subjects well outside her area of expertise, and often acts more as an advocate than an expert.

And yet Dr. Parisian appears to have FDA expertise, and some of her opinions are relevant to this case. Because it is not possible to address everything in her expert report, the Court is forced to paint with broad strokes.

A. Difficulties Presented by Dr. Parisian's Report.

Dr. Parisian's report lists hundreds of documents, deposition transcripts, and expert reports she reviewed in preparing her opinions. Doc. 7312 ¶¶ 10-14. Dr. Parisian provides an overview of the FDA's 510(k) clearance process in general and as it relates

to IVC filters. *Id.* ¶¶ 17-76. Then, over the next 200 or so pages, she states the following opinions:

- Opinion 1: Bard's premarket actions with design and development of the Recovery filter as a permanent filter were inadequate (¶¶ 77-210);
- Opinion 2: Bard obtained FDA clearance to market the Recovery filter as both a permanent and retrievable IVC filter yet failed to provide physicians and patients with adequate warnings (¶¶ 211-346);
- Opinion 3: Bard's actions for post-market oversight continued to permit marketing of the flawed Recovery filter (¶¶ 347-456);
- Opinion 4: Bard developed its "next generation" of IVC filters based on piecemeal reactive modifications to its flawed Recovery filter platform rather than use of quality science and design principles (¶¶ 457-651);
- Opinion 5: Bard's quality systems and post market monitoring procedures were flawed, helped underestimate risk, and permitted continued commercial release of misbranded and dangerous products as supported by Bard's receipt of an FDA 2015 warning letter (¶¶ 652-673);
- Opinion 6: Bard engaged in aggressive off-label promotions which overstated benefits, downplayed risks, expanded the implanted patient population, and failed to adequately warn physicians, patients, and its own sales force of the risks (¶¶ 674-742);
- Opinion 7: Bard marketed the Recovery Cone Retrieval System as part of the Recovery IVC filter system to facilitate filter retrieval without having obtained 510(k) clearance (¶¶ 743-758).[2]

Each of these opinions is followed by a string cite of various FDA regulations, without explanation, and by a lengthy discussion of documents, depositions, events, and other facts regarding alleged flaws in Bard IVC filters, what Bard knew or should have known about those flaws, and what Bard failed to disclose to the FDA and the medical community. Doc. 7312 at 37-255. Dr. Parisian largely fails to explain how her factual recitations relate to or support her opinions. Nor does she explain how the facts relate to

[2] Dr. Parisian submitted a fifty page supplemental report that offers six of these opinions with regard to the Meridian and Denali filters. Doc. 7312-1.

her string cites of regulations. On the rare occasion where she states that Bard violated a specific regulation with some specific action, she fails to explain why that regulation was violated. *See* Doc. 7312 ¶¶ 343, 665.

Other courts have encountered similar problems with Dr. Parisian's opinions. In *Trasylol*, the court found that "[a]ll of Dr. Parisian's opinions suffer from this fatal flaw: she recounts [the] regulatory history, the contents of [defendants'] internal documents and e-mails, and the findings of scientific studies; she then offers a broad opinion, often outside her scope of expertise, that is not connected to the underlying facts in any apparent way and that lacks regulatory analysis." *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1347 (S.D. Fla. 2010); *see also Lopez*, 2011 WL 1897548, at *10 ("Dr. Parisian's report simply presents a narrative of selected regulatory and corporate events and quotations and then leaps to a conclusion without sufficient explanation"); *Miller v. Stryker Instruments*, No. CV-09-813-PHX-SRB, 2012 WL 1718825, at *11 (D. Ariz. Mar. 29, 2012) (Dr. Parisian provides "no analysis or explanation of [her] conclusory opinion" that the defendant violated FDA regulations); *Kaufman v. Pfizer Pharm., Inc.*, No. 1:02-CV-22692, 2011 WL 7659333, at *9 (S.D. Fla. Aug. 4, 2011) ("Dr. Parisian generally takes a collection of facts, imputes [defendants'] motive and knowledge to those facts, and draws unsupported conclusions that are unrelated to any regulatory experience that she has"); *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011) (Dr. Parisian's testimony is "riddled with conclusory statements lacking either analysis or explanation; improperly touches on issues well beyond [her] qualifications; and at times, merely regurgitates factual information that is better presented directly to the jury"); *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. July 8, 2008) (Dr. Parisian "testified to the bottom line without any explanation, failed to provide expert analysis, . . . testified in areas beyond her expertise, and invaded areas that required no expert testimony"); *Jacob v. Ceasars Entm't, Inc.*, No. 05-0805, 2007 WL 594714, at *4 (E.D. La. Feb. 21, 2007) ("Although [Dr. Parisian is] qualified by education, training and experience to render

opinions, [her] opinions are not based on sufficient facts or data, and the methodology used by [her] is unreliable").

B. The Parties' Positions.

Defendants argue that Dr. Parisian's testimony should be excluded entirely. They assert that she is an advocate, not an expert; she improperly opines on filter design and testing and on issues of medical causation; she provides testimony outside the scope of proper expert opinions, including factual narratives, legal conclusions, and speculation on Bard's intentions and ethics; and her opinions lack a coherent methodology. Doc. 7814.

Plaintiffs state that they intend to use Dr. Parisian to provide testimony on several specific subjects: (1) the role, procedure, and function of the FDA in its oversight of medical device manufacturers; (2) the duties and responsibilities of Bard to obtain FDA clearance for its IVC filters and to market safe and effective devices; (3) the duties and responsibilities Bard has under FDA rules to protect consumers of its products by monitoring device performance and communicating the risks attendant to the use of its devices to the public and physicians; (4) the process by which manufacturers apply for, document, and obtain regulatory clearance for devices such as IVC filters; (5) Bard's continuing duty to maintain expertise about its product and investigate risks related to its product; (6) the adequacy of Bard's pre- and post-market study, design, testing, validation, and monitoring of its retrievable IVC filters, starting with the Recovery filter; and (7) Bard's specific failures to comply with its duties under FDA regulations. Doc. 7184 at 6-7.

Unfortunately, Plaintiffs' description of these opinions bears little resemblance to Dr. Parisian's report. Her report ventures far beyond these subjects. As only a few examples, Dr. Parisian frequently states opinions on Bard's intentions and motivations, as though she were an expert on corporate psychology or strategy and internal Bard philosophies. She opines, for example, that Bard made IVC changes "in a piecemeal and reactive fashion heaped onto a flawed underlying [Recovery filter] platform with a goal to address physician perceptions about improvement to the prior generation of product.

. . . Bard's evolution of changes starting with the [Recovery filter] were not primarily made to improve quality, safety, and efficacy, or to protect patients but rather primarily to address sales force and physician perceptions about device problems and help keep and expand market share." Doc. 7312 at 162. She thus opines on *why* Bard took particular actions, a subject clearly not within her FDA expertise. Dr. Parisian also freely opines on Bard's intention in renaming some of its filters, asserting that it was done to "address lukewarm sales and waning physician support." *Id.* at 207. She offers opinions on the nature and sufficiency of corrosion testing, a matter well beyond her expertise. *Id.* at 218. These kinds of opinions are sprinkled through pages of factual narrative that often read more like a lawyer's closing argument than an expert's considered opinion. As noted in the case parentheticals set forth above, many courts have encountered this tendency on the part of Dr. Parisian, and many have excluded her testimony because of it.

Apparently aware that her report ventures beyond proper expert testimony, Plaintiffs set forth several concessions in their response to Defendants' motion. These include the following:

- Dr. Parisian "is not being proffered to testify in a narrative form[,]" and "the factual materials considered . . . are not intended to be the subject of her testimony in and of themselves." Doc. 7814 at 12, 16.
- Dr. Parisian "will not express any opinions on Bard's intent, motives, or state of mind." *Id.* at 12.
- "Dr. Parisian is not an engineer and cannot testify as to alternative designs or design defects in Bard's IVC filters." *Id.* at 14.
- Dr. Parisian "is not a medical specialist in areas relevant to causation issues in this case, such as interventional radiologist, cardiologist, internal medicine doctor, or hematologist. Plaintiffs thus concede that, to the extent that any opinion offered by Dr. Parisian at trial could be reasonably construed as being an opinion only on . . . 'causation' that Dr. Parisian will not offer such testimony." *Id.*

What, then, should the Court do with an overly broad and unwieldy report that in large respects is inconsistent with Plaintiff's description of how they intend to use Dr. Parisian at trial? It is not possible for the Court to parse her 257-page report, identifying which opinions are admissible and which are not, nor have the parties provided arguments that would enable the Court to do so. Faced with this difficulty, the best the Court can do is identify general areas within which Dr. Parisian will be permitted to testify and the general restrictions that will be placed on her at trial. More precise line-drawing must occur during trial.

C. The Court's Rulings on Dr. Parisian.

1. Plaintiffs' Concessions.

The Court accepts and agrees with each of Plaintiffs' concessions set forth in the bullet points above. Dr. Parisian will not be allowed to present a factual narrative at trial; to express opinions on Bard's intent, motives, or state of mind; to testify on alternative designs or design defects; or to testify on medical causation issues. Nor will she be permitted to testify on manufacturing or testing defects in Bard processes or about expectations or practices of physicians and patients with which she is not personally familiar. Dr. Parisian is not qualified by training or experience to testify on these matters as required by Rule 702.

2. Permitted Areas of Testimony.

Dr. Parisian will be permitted to testify about FDA practices and the 510(k) process as set forth at the beginning of her expert report. *See* Doc. 7312 at 21-36. Instruction on relevant matters beyond the understanding of a typical juror is an appropriate function of an expert witness. *EEOC v. S&B Indus., Inc.*, No. 3:15-CV-0641-D, 2017 WL 345641, at *4 (N.D. Tex. Jan. 24, 2017) ("If an expert distills a complicated subject into language a jury can understand, and that subject is relevant, she can be admitted as a 'teaching witness.'"). Dr. Parisian will also be permitted to testify regarding Bard's participation in the 510(k) process and its compliance with that process. *See In re C. R. Bard, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, 948 F. Supp. 2d 589, 629

(S.D. W. Va. 2013) (allowing regulatory expert to offer testimony regarding "the FDA 510(k) framework and process [and] Bard's actions taken with respect to this framework and process"); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 481-82 (S.D.N.Y. 2016) ("Dr. Parisian's testimony regarding the complex FDA regulatory framework [and the defendant's] compliance with FDA regulations . . . [is] relevant to this case and would be helpful to the jury."). Although it is difficult to draw precise lines, Dr. Parisian generally will be permitted to testify on the seven specific subjects identified in Plaintiffs' response, as quoted above (Doc. 7184 at 6-7), provided those opinions are disclosed in her expert report or deposition. *See* Case Management Order No. 8, Doc. 519, ¶ (I)(B).

3. Dr. Parisian's Methodology.

Defendants assert that Dr. Parisian has failed to identify the methodology used to arrive at her opinions. Rule 702 requires that expert testimony be "the product of reliable principles and methods." Fed. R. Evid. 702(c). Dr. Parisian describes her methodology as follows:

> I have used the same methodology I was trained to use at the FDA to reach the opinions discussed in this report regarding the design, development, and promotion of "retrievable" [Bard IVC filters]. I have continuously used this same methodology since 1991. This process included analyses of Bard's communications with the FDA during the 510(k) clearance process, as well as Bard's internal product development documents for both Bard's retrievable IVC filters and the Simon Nitinol Filter permanent IVC filter, which Bard asserted was also the predicate for its temporary IVC filters. My review included Bard's postmarket investigation of adverse events, manufacturing and design issues with its commercial permanent and retrievable filters, and its communications of risks and benefits to its sales force, physicians, key opinion leaders, the FDA, and patients.

Doc. 7312 ¶ 9.

To summarize this description, Dr. Parisian conducted "analysis" and "review" of various communications and documents. Although this description of methodology clearly is insufficient, it makes more sense when read in light of Dr. Parisian's

qualifications and her description of the 501(k) process. Dr. Parisian states that during her time at the FDA (1991 to 1995) she was primarily assigned to the Center for Devices and Radiological Health ("CDRH"). *Id.* at 9, ¶ 1. She also provided regulatory support to the FDA's Office of Compliance and Office of Device Evaluation ("ODE"). *Id.* at 9, ¶ 2. She was responsible for reviewing "adverse event reports and medical literature, and review of product labeling, promotions, advertising, and corporate records as to compliance with the Food, Drug and Cosmetic Act." *Id*. Her assignment "specifically included identification and mitigation of safety issues for the public." *Id*. Her report explains that the CDRH has a role in reviewing product modifications of already cleared devices, changing market claims, addressing safety and performance issues, or helping clear a new generation of devices or technologies. *Id.* at 21, ¶ 18. The ODE's role is pre-market clearance, which was the process by which Bard filters were cleared for sale. *Id*.

When Dr. Parisian's role in these FDA processes are understood, her methodology makes more sense. She appears to be saying that she engaged in the same kind of fact and document analysis in this case that she used when assigned to CDHR and when she provided regulatory support for ODE. Thus, it appears that Dr. Parisian is looking at relevant information from the eyes of an FDA regulator. This certainly is an area of specialized experience or training, and it could be helpful to the jury in understanding the FDA-related evidence that will be presented at trial and the significance of FDA's clearance of Bard's filters. *See Bard Pelvic Repair Sys.*, 948 F. Supp. 2d at 629. If done in a manner consistent with FDA practices, it could constitute a reliable method for rendering opinions as required by Rule 702(c). Thus, although Dr. Parisian's description of her methodology could be clearer, the Court concludes from her report as a whole that her methodology is sufficient to support opinions on FDA procedures and practices and Bard's compliance with those procedures and practices. *See Block v. Woo Young Med. Co.*, 937 F. Supp. 2d 1028, 1047 (D. Minn. 2013) ("[T]he Court finds that Dr. Parisian's opinions are supported by a sufficiently reliable methodology. She has grounded her opinions in sources including Woo Young's internal documents, pertinent scientific

literature, and publicly available documents, as well as her expertise."); *Fosamax v. Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009) ("Dr. Parisian has drawn conclusions about Merck's conduct based on her review of pertinent portions of the regulatory filings for Fosamax and Merck's internal company documents. This is the methodology she applied as a Medical Officer[.]").

4. Legal Conclusions.

The Ninth Circuit "has repeatedly affirmed that 'an expert witness cannot give an opinion as to her *legal conclusion*, i.e., an opinion on an ultimate issue of law.'" *United States v. Diaz*, --- F.3d ----, 2017 WL 6030724, at *2 (9th Cir. Dec. 6, 2017) (citations omitted; emphasis in original). "This prohibition of opinion testimony on an ultimate issue of law recognizes that, 'when an expert undertakes to tell the jury what result to reach, this does not *aid* the jury in making a decision, but rather attempts to substitute the expert's judgment for the jury's.'" *Id.* Given this prohibition, Dr. Parisian will not be permitted to provide legal conclusions concerning Plaintiffs' state law tort claims. For example, she will not be allowed to opine that Bard failed to adequately warn physicians of risks associated with Bard filters. *See* Doc. 7312 at 125, 241.

That is not to say, however, that Dr. Parisian and other qualified regulatory experts are precluded from offering opinions related to FDA procedures. Because FDA procedures are beyond the ken of average jurors, it will be helpful to have Dr. Parisian, or another qualified regulatory expert, describe how the 510(k) process works, how a manufacturer navigates the process, and how the FDA renders a decision based on the process. *See In re Yasmin & YAZ Prods. Liab. Litig.*, MDL No. 2100, 2011 WL 6302287, at *12 (S.D. Ill. Dec. 16, 2011) ("Dr. Parisian's testimony is permissible because of the complex nature of the [FDA] process and procedures and the jury needs assistance understanding it."). This description necessarily will entail a discussion of relevant FDA regulations and the legal requirements they may impose on manufacturers. This Circuit has noted that "it is sometimes impossible for an expert to render his or her opinion on a subject without resorting to language that recurs in the applicable legal

standard." *Diaz*, 2017 WL 6030724, at *3.

It also may be appropriate for a regulatory expert to opine as to what the FDA did in this case, and whether the FDA would have cleared a particular filter or label had certain facts been disclosed. Dr. Parisian's testimony in this regard may be relevant and necessary for Plaintiffs to rebut Defendants likely assertion that they are not liable because they complied with FDA procedures and ultimately received clearance for each filter and label.[3]

5. Preemption.

Defendants contend that Dr. Parisian's opinions regarding regulatory compliance are preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Doc. 7308 at 12-13. But *Buckman* is a "claim preemption case focusing on fraud-on-the-FDA claims, not an evidence preemption case." *Yasmin*, 2011 WL 6302287, at *11. Plaintiffs have made no claim of fraud on the FDA, and, with one possible exception, Plaintiffs' state law tort claims do not exist solely by virtue of the FDCA. *See* Doc. 303-1 ¶¶ 166-338.[4] The Supreme Court has made clear that federal law does not prevent juries in failure to warn cases from considering a manufacturer's compliance with FDA regulations. *Wyeth v. Levine*, 555 U.S. 555, 569-73 (2009). In short, evidence of regulatory compliance in this case is not preempted. *See In re Incretin-Based Therapies Prods. Liab. Litig.*, No. 15-56997, 2017 WL 6030735, at *2 (9th Cir. Dec. 6, 2017) ("Neither *Buckman*'s holding nor what the district court termed the 'policy underlying *Buckman*' can be read to preclude the discovery of evidence relevant to the plaintiffs' state-law failure to warn claims.") (citing *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc)); *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040-41 (9th Cir.

[3] Plaintiffs apparently intend to argue that the Court should preclude Defendants from presenting FDA evidence and making such arguments. If the Court limits Defendants' FDA evidence, it likely will also limit Plaintiffs' FDA evidence. That is a matter that must be addressed at trial.

[4] The Court granted summary judgment on the negligence per se claim asserted in the Booker case because no violation of any state statute was alleged and the claim therefore relied solely on the FDCA and ran afoul of 21 U.S.C. § 337(a). Doc. 8874 at 14-17.

2015) (rejecting the defendant's preemption argument and proposition that "any use of federal law to establish a standard of care is an attempt to enforce the underlying federal provisions"); *In re Vioxx Prods. Liab. Litig.*, 401 F. Supp. 2d 565, 587 (E.D. La. 2005) (*Buckman* does "not bar a qualified expert from testifying as to their opinion on whether the FDA correctly balanced the benefits and risks of a drug from a regulatory standpoint").

6. Control of Dr. Parisian at Trial.

Defendants' concerns about Dr. Parisian's tendency to provide lengthy factual narratives, argumentative testimony, and opinions beyond her area of expertise appear to be well founded. Dr. Parisian will not be allowed to engage in such practices at trial. Upon appropriate objections or to avoid clear error, the Court will limit her testimony to opinions within the area of her FDA expertise, terminate extended narratives, strike argumentative answers, and not permit unfounded opinions or ultimate legal conclusions. Plaintiffs' counsel should prepare Dr. Parisian to stay with the bounds of her expertise and to avoid unwarranted narrative or argumentative answers.

So limited, the Court concludes that Dr. Parisian's FDA expertise and opinions satisfy Rule 702. The Court will grant in part and deny in part Defendants' motion. The motion is granted with respect to the areas identified above in paragraph (C)(1). The motion is denied with respect to testimony within her area of FDA expertise. More precise decisions will be made at trial.

IV. Dr. Kessler.

As a medical doctor, professor of food and drug law, and former FDA Commissioner, Dr. Kessler is qualified to opine on regulatory issues that relate to Bard IVC filters. *See In re Xarelto Prods. Liab. Litig.*, MDL No. 2592, 2017 WL 1352860, at *2-3 (E.D. La. Apr. 13, 2017) (discussing Dr. Kessler's qualifications). In his expert reports, Dr. Kessler describes how Bard obtained premarket clearance for its Recovery and G2 filters under the 510(k) process, and explains that this process requires a showing of substantial equivalence to a predicate device and not independent proof of safety and

effectiveness. Generally speaking, Dr. Kessler offers the following opinions about Bard's filters and regulatory conduct: Bard failed to comply with FDA regulations, disclose adverse information to the FDA, and otherwise assure the safety and effectiveness of the Recovery and G2 filters; Bard filters present unacceptable risks to patients; Bard made misleading statements about the design and performance of its filters; the FDA would not have cleared the Recovery filter had Bard provided adequate disclosures; Bard failed to remove the Recovery filter from the market despite its increased risks; Bard failed to adequately warn physicians and patients about known filter complications; and Bard's strategy to design filters to be retrievable, but market them for permanent use, put patients at risk. Doc. 7313.

Defendants' primary challenge to Dr. Kessler's opinions is that he offers improper legal conclusions. Doc. 7309 at 3-7. Defendants also object to his factual narratives and his opinions about what the FDA would have done with allegedly withheld information; IVC filter design, testing, and causation; and Bard's intent and ethics. *Id.* at 7-13. The Court will address each argument in turn.

A. Legal Conclusions.

As explained above, an expert witness may not opine on an ultimate issue of law. *See Diaz*, 2017 WL 6030724, at *2. Thus, Dr. Kessler will not be permitted to provide ultimate legal conclusions concerning Plaintiffs' state law tort claims. *See Bard Pelvic Repair Sys.*, 948 F. Supp. 2d at 629 ("The questions of whether Bard's . . . products were not reasonably safe, . . . or whether Bard failed to warn, are questions for the jury, not Dr. Kessler."). Dr. Kessler may, however, offer opinions concerning the FDA regulatory process and Bard's compliance with the process. *See Wells v. Allergan, Inc.*, No. CIV-12-973-C, 2013 WL 7208221, at *1 (W.D. Okla. Feb. 4, 2013) ("Dr. Kessler may *not* testify as to the elements of a strict liability or negligence claim under Oklahoma law but *may* testify as to the law governing FDA regulations.") (emphasis in original); *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14-C 1748, 2017 WL 1836443, at *15 (N.D. Ill. May 8, 2017) ("[The] plaintiffs' claims are based on state law

doctrines such as negligence, failure to warn, strict products liability, breach of warranty, and fraud. The ultimate conclusions a jury will have to draw are rooted in state law, not federal law. And Dr. Kessler's testimony does not cover the ultimate issues that the jury will decide; rather, it concerns . . . FDA regulations. This is neither irrelevant [nor] improper[.]"). Plaintiffs avow that Dr. Kessler is well aware of his limited role as an expert on FDA regulatory matters and will not offer impermissible legal conclusions or instruct the jury on the law. Doc. 7805 at 11-13. The Court will hold Plaintiffs to their word, and is confident Defendants will object if Dr. Kessler crosses the line into inadmissible legal conclusions.

Defendants contend that given Dr. Kessler's impressive credentials, Plaintiffs will present him to the jury as the ultimate authority on FDA matters. Doc. 7309 at 2-3. One court recently noted that this argument seems to be that Dr. Kessler is *too* qualified to testify. *Testosterone*, 2017 WL 1836443, at *15. Plaintiffs note, correctly, that being well qualified is no basis for precluding the expert's opinions under Rule 702. Doc. 7805 at 13. Plaintiffs also make clear that Dr. Kessler will not purport to be a current FDA official or present his opinions as having the "imprimatur" of the FDA. *Id.* at 13 n.5. If Dr. Kessler attempts to do so at trial, Defendants may object and make the record clear through cross-examination. *See Testosterone*, 2017 WL 1836443, at *15 ("if an expert comes across as a know-it-all, he tends not to be believed, and cross-examination is a sufficient check"). Moreover, the jury will be informed that the Court, not Dr. Kessler nor any other witness, will instruct the jury on the law.

B. Narrative Testimony.

Defendants contend that Dr. Kessler's reports and attached schedules constitute a sprawling factual narrative, and his testimony at trial will serve only as an impermissible end-run around the orderly admission of evidence. Doc. 7309 at 7-9. But Defendants may object at trial if Dr. Kessler begins simply regurgitating facts instead of using relevant facts to support for his expert opinions. *See Wells*, 2013 WL 7208221, at *2; *In re Actos Prods. Liab. Litig.*, No. 12-cv-00064, 2014 WL 120973, at *10 (W.D. La.

Jan. 10, 2014) ("The objection that testimony is 'narrative' is an objection as to form, foundation, or responsiveness, and must be presented at trial."). Furthermore, the Court notes that narrative testimony is appropriate in some circumstances. *See Yasmin*, 2011 WL 6302287, at *13; *Testosterone*, 2017 WL 1836443, at *15. Whether it will be proper during any part of Dr. Kessler's testimony must be determined at trial.[5]

C. Opinions on Bard's FDA Disclosures.

Defendants contend that Dr. Kessler's opinions about what the FDA may have done with additional information are irrelevant and speculative. Doc. 7309 at 9-10. But such testimony is relevant to Defendants' defense that they are not liable because the FDA gave its blessing to Bard filters and labels. And, as a former Commissioner of the FDA, Dr. Kessler is qualified to opine about what a reasonable FDA official would have done with additional information. His testimony concerning these matters is sufficiently reliable for purposes of admissibility under Rule 702. *See Yasmin*, 2011 WL 6302287, at *13; *Bard Pelvic Repair Sys.*, 948 F. Supp. 2d at 630 ("Dr. Kessler may offer expert opinions related to Bard's disclosures to the FDA, as long as his opinions do not impermissibly draw legal conclusions."); *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, at *19 (E.D. Pa. Feb. 1, 2001) (regulatory expert was "qualified to testify as to what reasonable FDA officials . . . would do with adverse event information"). Whether it is relevant will depend on the nature of Defendants' FDA defense.[6]

D. Opinions on IVC Filter Design, Testing, and Causation.

Defendants object to Dr. Kessler opining on the design and testing of IVC filters.

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[5] In their reply brief, Defendants cite cases for the proposition that Dr. Kessler's report has an "analytical gap" between his factual narratives and regulatory analysis. Doc. 8231 at 4-5. But those cases were addressing the reports of Dr. Parisian, not Dr. Kessler. *See Trasylol*, 709 F. Supp. 2d at 1347; *Lopez*, 2011 WL 1897548, at *10; *Mirena*, 169 F. Supp. 3d at 478; *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-cv-144, 2015 WL 13022172, at *9 (S.D. Ohio Oct. 2, 2015) (S.D.N.Y. 2016). Defendants cite no case that has excluded Dr. Kessler from testifying at trial based on an unreliable methodology or failure to reliably apply the method to the facts of the case. Nor did Defendants raise this analytical-gap issue in their motion.

[6] Defendants' contention that Dr. Kessler's opinions are preempted under *Buckman* (Doc. 7309 at 10-11), is without merit for reasons set forth above.

Doc. 7309 at 11-12. Plaintiffs concede that Dr. Kessler is not qualified to opine that Bard filters were defectively designed, and contend that he is not directly testifying about the adequacy of Bard's testing. Doc. 7805 at 20. Plaintiffs claim that Dr. Kessler discusses filter specifications only in the context of his opinions regarding regulatory compliance. *Id.*

The Court cannot, on the present record, determine whether any specific testimony in this regard should be excluded. Defendants may object at trial if they believe Dr. Kessler is offering impermissible opinions as to the design or testing of Bard filters.

Defendants also object to any opinion that Bard failed to warn physicians about an increased risk of filter complications. As explained above, Dr. Kessler may not render legal conclusions concerning Plaintiffs' state law claims, including the failure to warn claim. The Court may permit Dr. Kessler, as an FDA expert, to opine that the FDA would not have cleared a particular warning if certain information had been disclosed, but Dr. Kessler may not venture outside his area of expertise and opine about the warnings a manufacturer should have given physicians practicing in a specialized area of medicine for purposes of state tort law. *See Bard Pelvic Repair Sys*, 948 F. Supp. 2d at 629.

E. Opinions Regarding Intent and Ethics.

Defendants argue that Dr. Kessler should not be allowed to opine about Bard's intent or ethics. Doc. 7309 at 12-13. The Court agrees. "Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony." *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004). Similarly, "[p]ersonal views on corporate ethics and morality are not expert opinions." *In re Baycol Prods. Liab. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007). Neither Dr. Kessler, nor any other expert (on either side of the case), will be permitted to opine on intent or ethics. *See In re Diet Drugs*, No. MDL 1203, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000) (excluding testimony that a pharmaceutical company's conduct was motivated by a desire to increase profits); *Testosterone*, 2017 WL 1836443, at *15 ("[Dr. Kessler] offers a framework by which the jury can assess what [the manufacturer] intended via its

marketing. But although Dr. Kessler may walk up to this line, he may not cross it; he cannot offer an opinion or conclusion about what [the manufacturer] intended.").

F. Summary for Dr. Kessler.

Dr. Kessler is qualified to opine on FDA regulatory issues that relate to Bard filters, and his testimony in this regard would prove helpful to the jury. But no expert, including Dr. Kessler, will be permitted to give ultimate legal opinions on state law claims, improperly narrate or regurgitate facts, or speculate about motives or intent.

IT IS ORDERED that Defendants' motions to exclude the opinions Drs. Suzanne Parisian and David Kessler (Docs. 7308, 7309) are **granted in part** and **denied in part** as set forth in this order.

Dated this 21st day of December, 2017.

David G. Campbell
United States District Judge